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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,025	11/03/2003	Stephen Bennett Elliott	1119-003	2143
27820 7590 06/15/2007 WITHROW & TERRANOVA, P.L.L.C. 100 REGENCY FOREST DRIVE SUITE 160 CARY, NC 27518			EXAMINER BOCKELMAN, MARK	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 06/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/699,025

Applicant(s)

ELLIOTT, STEPHEN BENNETT

Examiner

Mark W. Bockelman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7,9,11-15,17-20,22,24 and 26-45 is/are pending in the application.
- 4a) Of the above claim(s) 26-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,9,11-15,17-20, 22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's claims state that he provides biofeedback when the heart rate transitions from a maximum heart rate and from a minimum heart rate. According to applicant's specification, the biofeedback occurs when a peak or a trough (maximum or minimum) is detected on the heart rate variability trace and not a maximum/minimum in its normal meaning. A normal meaning provides one maximum heart rate and it can only be determined after all heart rates are determined. To the extent that applicant objects to the application of the Carlson reference and to what "biofeedback" means and to the extent that the claim language suggests that which is done in the Carlson reference, the examiner considers the claims rejectable under 112 first paragraph by applicant's own indication that such destroys the meaning of the terms. If applicant were to claim the patient to be detecting transitions from maximum and minimum peaks and troughs along a heart variability curve, the examiner would withdraw the first paragraph rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlson USPN 6,301,499. Carlson detects heart rates as well as changes in heart rates which includes changes that occur on a weekly basis. He thus detects transitions from yearly all time minimum and maximum values. The graph in figure 8a provides feedback as to when the yearly maximum and minimum occur as a biofeedback signal. He would also provide feedback through each week before averaging the values though not depicted.

Claims 1,3, 5, 7, 9, 11-15, 17-20, 22, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Vachillo USPN 5,997,482. Vachillo provides a feedback monitor that display current heart rates and would thus show graphically all changes in heart rate including maximum heart rates, minimum heart rates and transitions from maximums to minimums and also provides phase angles between breathing rate and heart rate at all such heart rates. The disclosure also suggests that breathing conditioning is used wherein a patient attempts to minimize phase differences between the breathing cycle and the heart rate cycle to match the peaks and troughs and thus the signal is one telling the patient when to inhale and exhale. The peaks on the rate monitor as well as the phase angle are thus considered to be the signal to indicate breathing changes. The feedback device also provides a feedback phase difference angle which is considered to be an offset value. All values are capable of being programmable and thus the term “programmable” alone offers no patentable distinction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3, 5, 7, 9, 11-15, 17-20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stabler et al USPN 6,836,681 .Friedman provide the patient with a heart rate variability monitor that shows peaks and troughs as well as heart rates that are offset from the maximum and minimums. Such values are capable of being programmed into a computer making them programmable values. Applicant's claims merely provide for a patient to watch the monitor, the claims do not specify a specific instruction or action of the patient to inhale or exhale only that the monitor trace indicates such is the time to be done. To have had the patient watch his own heart rate variability being monitored would have been obvious in view of Stabler so as to provide feedback to the patient to better control such.

Response to Arguments

Applicant's arguments filed 3-26-2007 have been fully considered but they are not persuasive. Applicant's argument's seem to focus in on the meaning of "biofeedback" Applicant implies that such feedback is necessarily immediate, yet as the claims are written now with the language used, it suggests that it can be immediate. The

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examiner refers applicant to the above discussion for the rejection of the claims under first paragraph. If applicant were to adopt the language that better expresses that which is shown in applicant's specification as suggest above and express the biofeedback being provided immediately to the patient the examiner would withdraw the rejection based upon Carlson. While applicant's claims use language that cover embodiments that differ from the normal meaning of words the examiner considers the application of Carlson to be fair game. In Varshillo, the patient watches a heart rate monitor. This is all that is required by applicant's claim 1. The heart rate monitor shows heart rates for each cycle and indicate to the patient when it speeds up by a shortening of the ecg trace and slows down by a lengthening. Applicant provides nothing different. If the heart rate increase from one cycle to the next a transition from a minimum has is conveyed because it is a minimum for that particular time frame.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached at 571 -272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark Bockelman
Primary Examiner
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June 11, 2007